Remarks

Claims 1-5 and 8-12 are currently pending.

Rejection under 35 USC 102(e)

The Examiner has maintained the previous rejection of claims 1-5 and 8-12 under 35 USC 102(e) as being unpatentable over Wasmoen et al. (U.S. Patent No. 5,770,211). In maintaining this rejection, the Examiner has refused to accord the present application the July 1, 1991, priority date of U.S. Patent Application No. 07/726,609 ("the '609 application") because the Examiner contends the '609 application fails to support more than one exogenous gene inserted into the thymidine kinase (TK) gene of the raccoon poxvirus genome.

Further, the Examiner has asserted that the Applicants, in a previous response (filed October 27, 2004), have taken out of context and misrepresented page 15, lines 25-28 of the '609 application.

For reference, lines 25-28, page 15, of the '609 application are reproduced below:

> " It is another aspect of the present invention to utilize the infectious raccoon poxvirus for expressing an exogenous gene from a second viral source and its use in the immunization of animals against the second virus."

The Examiner states::

> *"In context, it is clear that 'a second viral source' means nothing more than some other unknown viral gene may replace the disclosed and claimed VP2 gene insert; not that the gene expressing VP2 and another unknown viral gene are arranged in tandem with the TK gene."*

Applicants respectfully disagree with this assessment. In support, Applicants point out the paragraph immediately preceding the above text from lines 25-28 of page 15 states:

> "Accordingly, it is one aspect of the present invention to describe the successful insertion of an exogenous gene from one viral genome into a chimeric plasmid, and the transfection of this plasmid into the thymidine kinase portion of raccoon poxvirus." (Page 15, lines 21-24).

Under the Examiner's interpretation, the paragraph of lines 25-28 would essentially provide the same disclosure as the paragraph of lines 21-24 because each would disclose an infectious raccoon poxvirus comprising a single exogenous gene. Applicants assert that contrary to the Examiner's interpretation, while lines 21-24 disclose insertion of one exogenous gene, the meaning of lines 25-28 is that the an exogenous gene from a first viral genome as well as from a second viral genome is inserted into the raccoon poxvirus. Thus, Applicants believe there was no misrepresentation in the response filed on October 27, 2004.

Applicants further point out that in the October 27, 2004 Response, reference to page 15, lines 25-28 is made in the same parenthetical citation as reference to page 42, lines 13-23 of the '609 application, which state:

> "*Multivalent recombinant vaccines* are also within the scope of the present invention. For example, in addition to the feline parvovirus immunogen-producing DNA carried within the recombinant construct, additional immunogen-producing DNA elements from other disease causing viruses may be incorporated. For example, the raccoon poxvirus carrier genome may include 25 Kb of foreign DNA (the parvovirus insert is only approximately 2.5 Kb in length); it is therefore possible to provide additional DNA inserts form other disease causing viruses as, for example, hepatitis and/or herpes, and thus achieve protection to a number of different diseases *with a single recombinant viral inoculation.*" (Emphasis added; parenthesis in original.)

Again, Applicants assert there has been no misrepresentation of the disclosure of the '609 application. Rather, as described above, the '609 application expressly discloses multivalent recombinant raccoon poxvirus vaccines.

Additionally, the following claims indicate that insertion of multiple exogenous genes was clearly intended to be within the scope of the '609 application as filed, as is evident from claim 5. Claims 1 and 5 as filed are reproduced below.

> 1. A plasmid designated as PTKgptF3S and having an exogenous nucleic acid insert selected from an immunogen producing portion of the genome of a disease causing virus of animals.
>
> 5. A plasmid according to claim 1 in which the nucleic acid insert comprises at least one **additional** exogenous nucleic acid element selected from an immunogen-producing portion of the genome of a second disease causing virus of animals. (Emphasis added.)

Similarly, a recombinant raccoon poxvirus comprising more than one exogenous gene was clearly intended to be within the scope of the invention, as is evident from claim 8 of the '609 application as filed. Claims 7 and 8 of the application as filed are reproduced below.

> 7. An infectious animal virus capable of undergoing replication in an animal host and having a heterologous nucleic acid genome containing an exogenous nucleic acid element inserted within the genome and selected from the immunogen producing portion of the genome of a disease causing virus of animals.
>
> 8. A virus according to claim 7 wherein the genome contains at least one **additional** exogenous nucleic acid element inserted within the genome and selected from an immunogen-producing portion of the genome of a second disease causing virus of animals. (Emphasis added.)

Therefore, Applicants assert there has been no misrepresentation of the disclosure in the '609 application.

Further, the Examiner contends that the '609 application does not enable a multivalent recombinant raccoon poxvirus that contains more than one exogenous gene.

In response, Applicants point out that a chimeric plasmid used for inserting the parvovirus VP2 gene into a recombinant raccoon poxvirus genome by homologous recombination is described in Example I (pages 24-25) and is also graphically depicted in Figure 1 of the '609 application. From reading this portion of the specification, a skilled artisan would recognize that a chimeric plasmid comprising a second viral gene in addition to the VP2 gene could readily be prepared using techniques described in the '609 application and that were well known in the art at the time the '609 application was filed. Such would be recognized because preparing a chimeric plasmid comprising a second viral gene in addition to the VP2 gene would not require more than the routine preparation of a DNA fragment comprising the nucleotide sequence of both genes and inserting the fragment into a plasmid in essentially the same manner as disclosed for the VP2 gene alone in Example I.

Applicants further submit that one skilled in the art would know from the '609 specification that such a plasmid could readily be used to make a recombinant raccoon poxvirus comprising both genes inserted into the TK site of the virus. This is such because the '609 application discloses that the raccoon poxvirus genome may include 25 Kb of foreign DNA, but that the parvovirus insert is only approximately 2.5 Kb in length. Therefore, the '609 specification teaches that a raccoon poxvirus has suitable genomic capacity to permit the insertion of a DNA polynucleotide of sufficient length to encode both the parvovirus gene and a second exogenous gene.

Applicants further point out that insertion of a parvovirus gene into the recombinant raccoon poxvirus TK site using recombination between the chimeric plasmid of Example I and a raccoon poxvirus is described in Example II (pages 26-27) and is also graphically depicted in Figure 2 of the '609 application. Based on this disclosure, one skilled in the art would know how to recombine a chimeric plasmid comprising a VP2 gene and a second exogenous gene with a raccoon poxvirus to obtain a recombinant raccoon poxvirus comprising the both of these genes. This is such because one skilled in the art would know that homologous recombination is dependent on the

particular sequences that flank the insert (i.e., the TK sequences) which are homologous to the intended insertion site, rather than the sequence of the insert itself which does not directly participate in recombination. In this regard, whether the DNA fragment in a chimeric plasmid encodes one or more genes is essentially immaterial to recombining it with a raccoon poxvirus. Therefore, because one skilled in the art, upon reading the '609 specification, would know how to prepare a chimeric plasmid comprising more than one exogenous gene, and how to recombine that plasmid with a raccoon poxvirus at the TK site, the '609 specification fully enables a recombinant raccoon poxvirus comprising more than one exogenous gene inserted into its TK site.

Therefore, Applicants submit that the '609 application fully enables a recombinant raccoon poxvirus having more than one gene inserted into the TK site of the raccoon poxvirus genome and should be entitled to the filing date of the '609 application accordingly.

The Examiner also asserted that the '609 application fails to support the exogenous genes set forth in the Markush groups of instant claims 2 and 9. However, Applicants submit that the '609 application is enabled for a recombinant raccoon poxvirus comprising more than one exogenous gene inserted into the TK site and further point out that the '609 specification discloses inserting genes from feline infectious peritonitis virus, feline calicivirus virus, herpes virus and hepatitis virus in addition to FPV (page 42, lines 7-12).

Conclusion

Applicants submit that the instant application should be accorded the priority of the '609 application which was filed on July 9, 1991 because the '609 application fully enables one skilled in the art to make and use multivalent recombinant raccoon poxviruses comprising more than one exogenous gene inserted into the TK site. Based on this, Applicants respectfully request the Examiner to withdraw the cited reference and to allow all the pending claims.

Applicants herewith requests a two-month extension of time to file this response. A check for the required fee of $450.00 is enclosed. The Examiner is authorized to charge any additional amount due or credit any overpayment to Deposit Account no. 08-2442.

Respectfully submitted,

By: _____

John D. Lopinski, PhD., Reg. No. 50,846

HODGSON RUSS LLP
One M & T Plaza, Suite 2000
Buffalo, New York 14203-2391
Tel: 716-848-1628
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